within five years of the onset of clinical diabetes, reflecting a "burned out" autoimmune process. These data lend further support to the notion that PGS-2 is a primary monocyte defect in human IDD as it is in the NOD mouse.

Identification of PGS-2 as a primary defect enables the use of PGS-2 as an early cellular marker for IDD susceptibility. Differences in the PGS-2 gene of normal individuals and autoimmune subjects can be used to perform genetic screening of individuals to assess susceptibility to diabetes or other autoimmune disease.

Regardless of its status as a primary defect, PGS-2 expression reflects an active autoimmune process, and is highly advantageous in identifying individuals at high risk for IDD. In this regard, PGS-2-positive individuals who produce the highest levels of PGS-2 have progressed to clinical diabetes the fastest. It is also known that autoimmune diseases progress into spontaneous remissions or exacerbations. PGS-2 expression can be used to identify and/or monitor such changes in disease activity, i.e., PGS-2 positivity reflecting higher levels of disease activity and loss of PGS-2 expression reflecting remission. This is of great importance in IDD, where no physical signs or symptoms manifest to suggest exacerbation of the autoimmune attack on the insulin-producing cells.

PGS-2 is expressed in a high percentage of monocytes from individuals with autoimmune disorders such as SLE and thyroiditis. Thus, PGS-2 expression in monocytes can be employed as a cellular marker for other autoimmune diseases in addition to IDD. Of note in screening healthy controls is one individual whose monocytes were strongly positive for PGS-2 expression, who had no personal or family history of autoimmune diseases. This individual, six weeks post-screening, developed Raynaud's phenomenon and a strongly positive ANA, suggesting the development of a collagen vascular disease. This further supports the utility of the subject invention for general screening for autoimmune dysfunction.

EXAMPLE 8

FACS Assay for PGS-2

One aspect of the invention is a fluorescent activated cell sorter (FACS) based assay for PGS-2 protein. Using this assay, it is possible to quantitate the percentage of cells in the peripheral blood that express the PGS-2 protein. This assay employs an antibody that specifically binds to the PGS-2 protein. The binding of this antibody to PGS-2 can be detected because the antibody is coupled to a fluorescent molecule which can be detected by the lasers of the FACS machine. Using this procedure, which requires only one-half teaspoon of blood, it is possible to detect the expression of PGS-2 protein in blood cells and determine the percentage of monocytes of pre-IDD individuals that constitutively express this enzyme.

EXAMPLE 9

Uses, Formulations, and Administrations

Application of the treatments of the subject invention can be accomplished by any suitable method and technique presently or prospectively known to those skilled in the art.

In one embodiment, compounds of the subject invention have effective immunomodulatory activity. Specifically, they are useful in regulating immune responses in animals and humans. Thus, pharmaceutical compositions containing compounds of the invention as active ingredients are useful in prophylactic or therapeutic treatment of an immunomodulatory response in humans or other mammals.

The dosage administered will be dependent upon the immunomodulatory response desired; the type of host involved; its age, health, weight, kind of concurrent treatment, if any; frequency of treatment; therapeutic ration and like considerations.

The compounds of the subject invention can be formulated according to known methods for preparing pharmaceutically useful compositions. Formulations are described in detail in a number of sources which are well known and readily available to those skilled in the art. For example, *Remington's Pharmaceutical Science* by E. W. Martin describes formulations which can be used in connection with the subject invention. In general, the compositions of the subject invention will be formulated such that an effective amount of the bioactive compound(s) is combined with a suitable carrier in order to facilitate effective administration of the composition.

In accordance with the invention, pharmaceutical compositions comprising an active ingredient and one or more non-toxic, pharmaceutically acceptable carrier or diluent.

The compositions of the invention are advantageously used in a variety of forms, e.g., tablets, capsules, pills, powders, aerosols, granules, and oral solutions or suspensions and the like containing suitable quantities of the active ingredient. Such compositions are referred to herein and in the accompanying claims generically as "pharmaceutical compositions." Typically, they can be in unit dosage form, namely, in physically discrete units suitable as unitary dosages for human or animal subjects, each unit containing a predetermined quantity of active ingredient calculated to produce the desired therapeutic or prophylactic effect in association with one or more pharmaceutically acceptable other ingredients, e.g., diluent or carrier.

It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and the scope of the appended claims.

I claim:

1. A method for inhibiting the development of an autoimmune disease wherein said method comprises the administration of TGF-β to an individual in need of such treatment; wherein said disease is insulin-dependent diabetes and wherein said method further comprises the administration of an antigen associated with diabetes.

2. The method, according to claim **1**, wherein said antigen is selected from the group consisting of insulin, GAD, IA-2, and antigenic fragments of these antigens.

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